

## **Quality Control of Idiopathic Scoliosis treatment in 147 patients while using the RSC brace**

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### **1. Introduction**

There are numerous different philosophies and design possibilities in the conservative treatment of idiopathic scoliosis (IS). Most importantly is that the goals of treatment are clearly defined. These are primarily to prevent the progression of the scoliotic deformity from the beginning to the end of the duration of treatment [1].

Many factors influence the course of treatment, which depend on the initial patient clinical presentation and brace compliance. Ultimately, the results by the completion of the growth phase, should present a reduced Cobb angle, improved trunk, shoulder and pelvic alignments as well as the accompanying change in the clinical presentation. The name of a scoliosis brace and design does not always represent a particular standard. In practice, it is often seen that patients are fit and delivered malfunctioning orthotic designs and shapes of well-known brands. Often these are paid for by health insurance providers without adequate follow-up of fit and function. Although there is significant information available for patients and their families, they are often left completely on their own with the diagnosis and therapy. However, presently it has been recognised how important it is to provide adequate scoliosis information and a solid treatment plan for scoliosis physical therapy.

The number of patients presenting with huge aesthetic and psychological problems due to large curvatures and all the resulting pathological mechanisms at the end of their growth phase could be significantly reduced if a correct and above all timely diagnosis were made.

Comprehensive support and communication should be provided to all interdisciplinary team members on the specific curve type, brace design, treatment protocol and follow-up process. This would improve the specific physical therapy program designed for the patient and optimize the brace fitting and function as well as the follow-up process and brace adjustments.

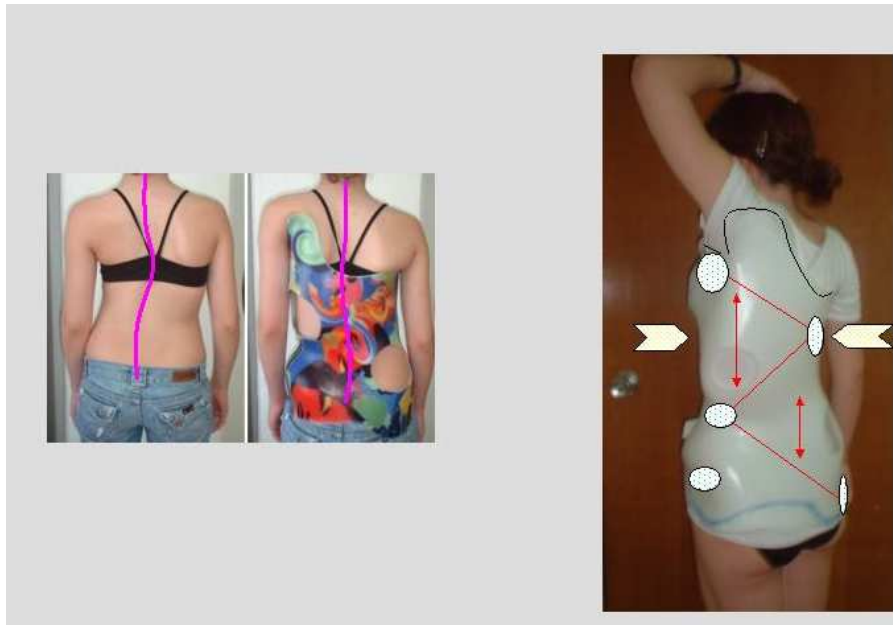
## **2. Treatment of Scoliosis**

Scoliosis is a multifactorial deformity which effects all 3 body planes of the trunk and spine, it presents as lateral curvature with torsion of the spine and chest, often associated with abnormal sagittal profile, such as flatback [2].

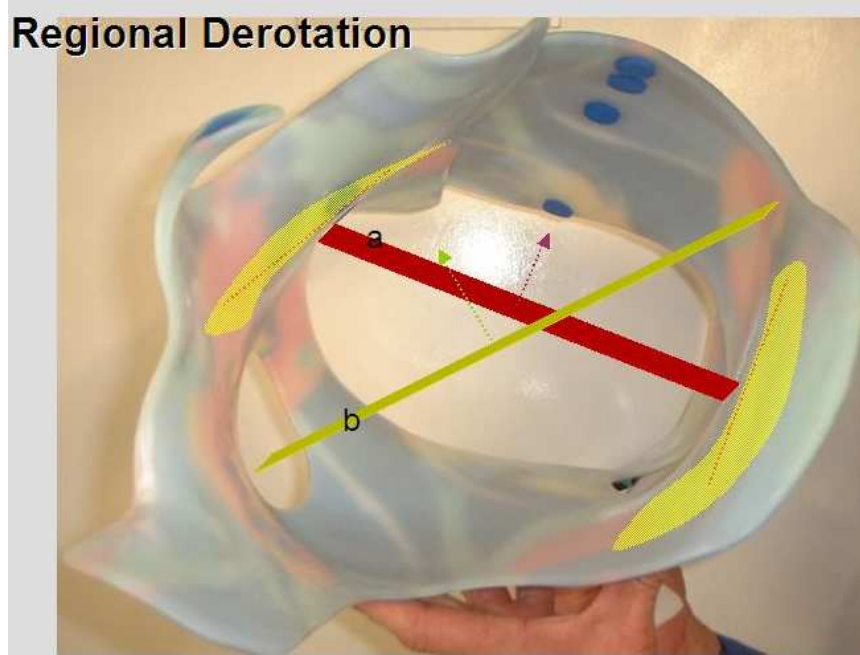
### **2.1 RSC Brace Design, Function and Classification**

The general correction principle of scoliosis was that of detorsion and sagittal normalisation, which would effectively correct the coronal plane, resulting in some elongation of the spine, without any significant distraction force [3,4,5,6]. The RSC brace was designed to follow this principle by means of pressure zones and expansion zones, which derotated different parts of the trunk. Normalisation of the sagittal profile was achieved from the derotation because the spine was coupled to the ribs in the thoracic area, and in the lumbar area it moved indirectly when the abdominal muscles were selectively pressed. The pressure zones were designed to provide corrective forces in the coronal and sagittal planes, acting as a three-point pressure system. Also, derotation was corrected in the transversal plane via pressure zones [7]. These three-dimensional pressure systems are illustrated further in figure 2.1, figure 2.2, and figure 2.3.

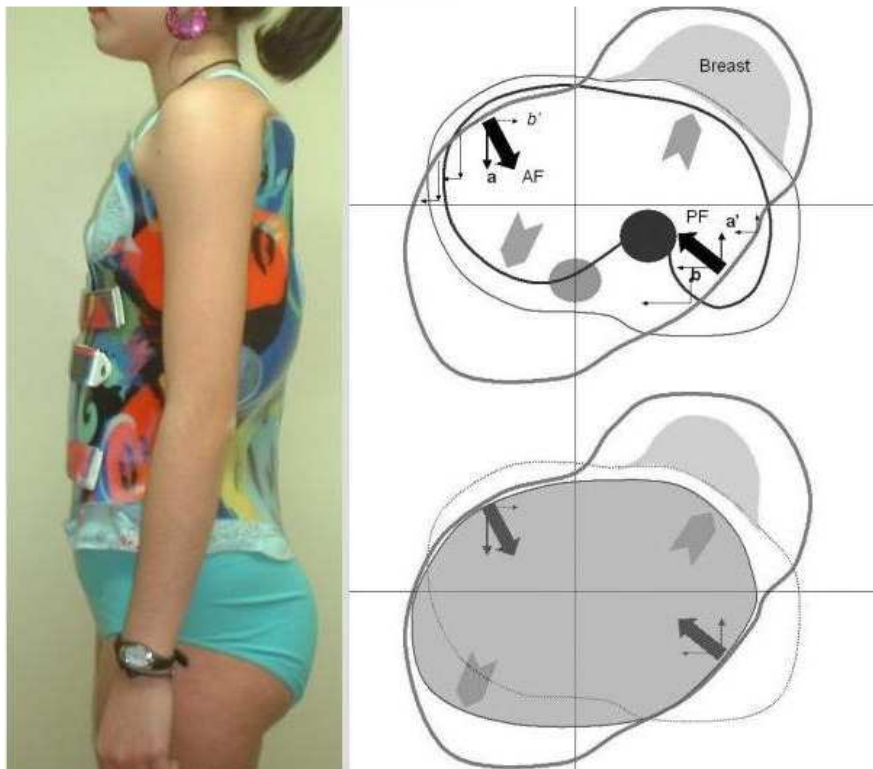
The Rigo classification is presently the only classification developed specifically for brace design, as opposed to other forms that adapted a classification that was developed initially for surgical decision-making. This classification is used in conjunction with the design of the Rigo System Chêneau brace (RSC brace), a derivative of the Chêneau brace [8,9,10].



**Figure 2.1 Frontal plane alignment and correction with the Rigo System Chêneau brace. Sagittal plane normalization and derotation are also achieved through elongation of the spine and ventral/dorsal pressure systems [11].**



**Figure 2.2 Derotation forces in the transverse plane acting at the thoracic (b) and lumbar (a) section. Note that there are large expansion areas that must be present for correction. In this particular case, there is a right ventral expansion space at the thoracic level and a left dorsal expansion space at the lumbar level [11].**



**Figure 2.3 Derotation at the thoracic level to achieve more physiological sagittal profile of the spine to reduce flatback [11].**

The specific design of the brace depends on the curve pattern observed in the frontal plane, however the transverse and sagittal plane deformities are taken into consideration as well; therefore, the brace design is modified accordingly. Clinical and radiological criteria are evaluated to determine the curve pattern [8,9,10]. These curve patterns along with their criteria are illustrated in figure 2.4 and figure 2.5.

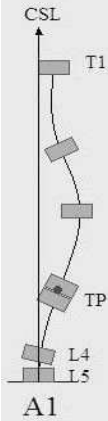
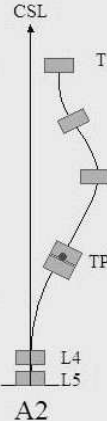
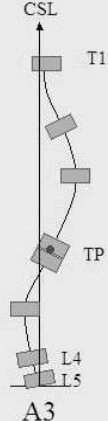
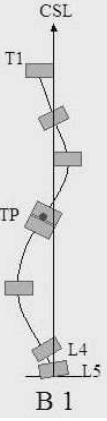
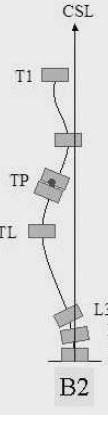
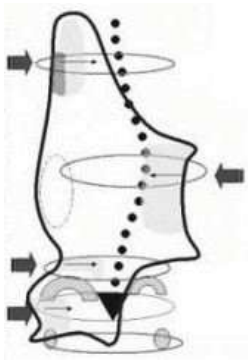
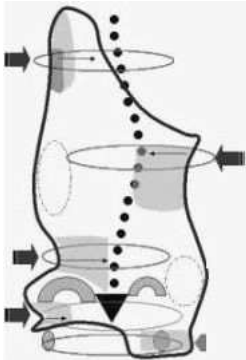
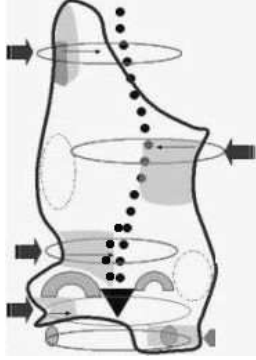
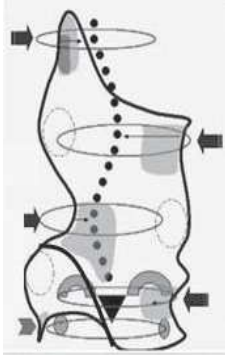
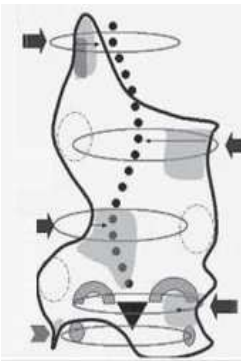
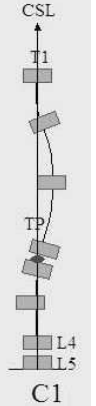
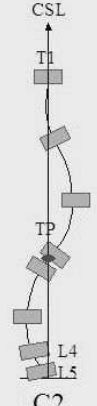
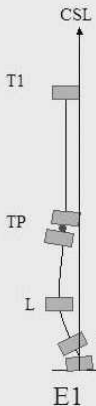
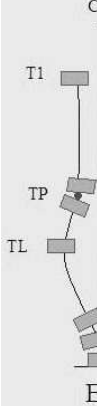
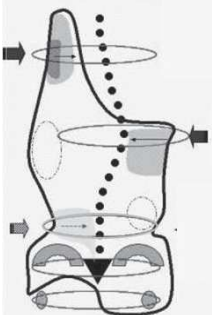
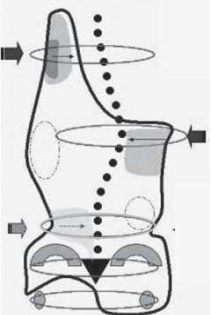
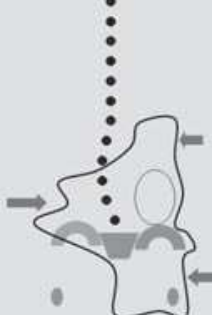

A1	A2	A3	B1	B2
<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave thoracic side</li> <li>• Trunk imbalance to the convex thoracic side</li> <li>• Long thoracic rib hump going down into the lumbar region</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave thoracic side</li> <li>• Trunk imbalance to the convex thoracic side</li> <li>• Noticeable rib hump/no lumbar or minimal lumbar prominence</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave thoracic side</li> <li>• Trunk imbalance to the convex thoracic side</li> <li>• Noticeable rib hump/minor lumbar prominence</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the convex thoracic side</li> <li>• Trunk imbalance to the concave thoracic side</li> <li>• Noticeable rib hump and lumbar or thoracolumbar prominence</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the convex thoracic side</li> <li>• Trunk imbalance to the concave thoracic side</li> <li>• Noticeable thoracolumbar prominence associated to a minor thoracic hump.</li> </ul>
<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single long thoracic/fractioned lumbar</li> <li>• TP imbalance to the convex thoracic side</li> <li>• T1 imbalance to the convex thoracic side</li> <li>• L4 horizontal or tilted to the convex side</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single thoracic/no or minimal functional lumbar</li> <li>• TP imbalance to the convex thoracic side</li> <li>• T1 imbalance to the convex thoracic side</li> <li>• L4 horizontal</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single major thoracic/lumbar minor</li> <li>• TP imbalance to the convex thoracic side</li> <li>• T1 imbalance to the convex thoracic side</li> <li>• L4 tilted to the concave thoracic side/negative L5-4 counter-tilting</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Double thoracic and lumbar or thoracic and thoracolumbar</li> <li>• TP imbalance to the concave thoracic side</li> <li>• T1 imbalance to the concave thoracic side</li> <li>• Positive L5-4 counter-tilting</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Major thoracolumbar combined with a minor thoracic curve</li> <li>• TP imbalance to the concave thoracic side</li> <li>• T1 imbalance to the concave thoracic side</li> <li>• Positive L5-4 counter-tilting (often, positive L4-3 counter-tilting)</li> </ul>
 <p>A1</p>	 <p>A2</p>	 <p>A3</p>	 <p>B 1</p>	 <p>B2</p>
<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• 3C 'Open pelvis on the convex thoracic side'</li> </ul> 	<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• 3C 'Classical'</li> </ul> 	<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• 3C 'Classical'</li> </ul> 	<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• 4C 'Classical' eventually pelvis open at the concave thoracic side</li> </ul> 	<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• 4C 'Classical'</li> </ul> 

Figure 2.4 A1, A2, A3, B1, and B2 Rigo curve types and corresponding RSC brace design based on specific clinical and radiological criteria [8,9].

C1	C2	E1	E2
<p><b>Clinical Criteria</b></p> <ul style="list-style-type: none"> <li>• Pelvis centered</li> <li>• Trunk balanced</li> <li>• Noticeable rip hump with lumbar spine rectilinear</li> </ul>	<p><b>Clinical Criteria</b></p> <ul style="list-style-type: none"> <li>• Pelvis centered</li> <li>• Trunk balanced</li> <li>• Noticeable rip hump combined with a noticeable lumbar prominence</li> </ul>	<p><b>Clinical Criteria</b></p> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave lumbar side</li> <li>• Trunk imbalance to the convex lumbar side</li> <li>• Noticeable lumbar prominence with no thoracic hump</li> </ul>	<p><b>Clinical Criteria</b></p> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave thoracolumbar side</li> <li>• Trunk imbalance to the convex thoracolumbar side</li> <li>• Noticeable thoracolumbar prominence with no thoracic hump</li> </ul>
<p><b>Radiological Criteria</b></p> <ul style="list-style-type: none"> <li>• Single thoracic with no lumbar curve</li> <li>• TP on CSL</li> <li>• T1 on CSL</li> </ul>	<p><b>Radiological Criteria</b></p> <ul style="list-style-type: none"> <li>• Thoracic major and lumbar minor or double thoracic and lumbar (false double)</li> <li>• TP on CSL</li> <li>• T1 on CSL</li> <li>• Negative L5-4 counter-tilting</li> </ul>	<p><b>Radiological Criteria</b></p> <ul style="list-style-type: none"> <li>• Single lumbar with no thoracic curve</li> <li>• TP imbalanced to the convex lumbar side according to CSL</li> <li>• T1 imbalanced to the convex lumbar side</li> </ul>	<p><b>Radiological Criteria</b></p> <ul style="list-style-type: none"> <li>• Single thoracolumbar with no thoracic curve</li> <li>• TP imbalanced to the convex thoracolumbar side according to CSL</li> <li>• T1 imbalanced to the convex thoracolumbar side</li> </ul>
 <p style="text-align: center;">C1</p>	 <p style="text-align: center;">C2</p>	 <p style="text-align: center;">E1</p>	 <p style="text-align: center;">E2</p>
<p><b>RSC Brace Design</b></p> <ul style="list-style-type: none"> <li>• Neutral pelvis</li> </ul> 	<p><b>RSC Brace Design</b></p> <ul style="list-style-type: none"> <li>• Neutral pelvis</li> </ul> 	<p><b>RSC Brace Design</b></p> <ul style="list-style-type: none"> <li>• Short lumbar brace</li> </ul> 	<p><b>RSC Brace Design</b></p> <ul style="list-style-type: none"> <li>• Short thoracolumbar brace</li> </ul> 

**Figure 2.5 C1, C2, E1, and E2 Rigo curve types and corresponding RSC brace design based on specific clinical and radiological criteria [Error! Reference source not found.].**

Further description of the Rigo classification is outlined by Rigo, Villagrasa and Gallo in, 2010 [8] and RSC biomechanical brace principles are outlined by Rigo and Weiss, 2008 [11] Rigo et al. documented in 2010 their findings on the intra- and inter-observer reliability of the Rigo classification. Wood in 2010 later presented at ISPO in Leipzig, Germany a detailed description of the Rigo classification and its reliability[9].

## **CHAPTER 3. METHODS**

### **3.1 DESIGN**

The experimental hypothesis predicted that those subjects who are treated with the RSC brace would report a significant primary correction of the major, minor, thoracic and lumbar Cobb angles for both the main and SOSORT restrictive criteria (RC) groups [12, 13].

### **3.2 SUBJECTS**

The main group consisted of 147 subjects with double curves ranging from 7 degrees to 65 degrees for the major Cobb angles and 1 degree to 60 degrees for the minor Cobb angles. There were 17 male and 130 female subjects, ages from 5 to 15. The 147 subjects were diagnosed with progressive idiopathic scoliosis and were treated by using a RSC brace which involved a medical team collaboration between MR in Spain, Ortholutions in Germany, and the exclusive RSC brace treatment center.

The SOSORT (RC) group included only 25 subjects that were selected from the main 147 subjects after the selective criteria outlined by SOSORT was applied. The criteria limited subjects to only those who were female, were at least 10 years old, presented clinical signs of



puberty, had Cobb angles from a minimum 25 degrees to maximum 35 degrees with Risser sign of 0 [12].

### **3.3 PROCEDURE**

Each subject had radiographs taken before brace treatment and with the RSC scoliosis brace at the six to eight week follow-up appointment. The radiographs taken six to eight weeks following treatment were taken with the subject wearing the RSC brace (i.e. “in-brace” radiographs). The Cobb angles were measured from these radiographs for comparison to obtain the primary correction results.

The Cobb angles for the thoracic and lumbar curves were noted before brace treatment and at the first in-brace X-ray. Also, the data was analyzed to compare major and minor curves, depending on which curve was larger and more structural. Mean Cobb angle values and standard deviations were determined among the subjects for both the main group and the SOSORT (RC) group.

From these results, the primary corrections were determined. A sample t-test was performed to determine the statistical significance of the results. The data was analyzed for both the main group of 147 subjects as well as the reduced SOSORT criteria group of 25 subjects.

### **3.4 RSC Scoliosis Brace Treatment**

The RSC® (Rigo System Chêneau) Management System is a patented method for producing computer standardized custom molded scoliosis braces for patients with scoliosis since 2001. This brace system is based off hand-made molds from Manual Rigo (MR) dating back from the early 1990s to present.

Treatment using a RSC brace involves a medical team collaboration between MR in Spain, Ortholutions in Germany, and the exclusive RSC brace treatment center.

Dynamic measurements which are taken with the patient in a corrected, extended posture. Also, static measurements taken to establish an exact CAD/CAM reproduction of an original Rigo brace [14].

The individual curve pattern and brace design for each patient is personally selected by MR, based on the x-rays and clinical photos (photos of the morphology and clinical presentation) of the patient. The biomechanical design of every specific curvature model is retained to 100%. The curve pattern is classified according to the classification of Rigo.

Next, the fabrication for each brace is custom-made and drawn from an extensive library of CAD CAM shapes of MR's own handmade molds. These custom made RSC braces are sent to the RSC certified treatment centers and fitted directly by trained teams.

All stages of treatment, including clinical photos with patient in and out of brace, x-rays and team notes are posted on a secure database. The subsequent brace fittings, follow up photos,

and in-brace x-rays are evaluated by MR and Ortholutions in collaboration with the RSC brace treatment center. This medical team approach optimizes the treatment and results. Complications and complex questions can also be discussed and clarified here at any time with the team of experts. Information and solutions to problems are passed on in a timely and straightforward manner. Through the communication platform, the system facilitates trained teams and optimizes treatment quality control through constant development in knowledge. The complete scoliosis bracing treatment protocol improves standards and reduces the number of bracing failures

At this moment patients treated with CAD CAM RSC braces in Germany have shown similar in brace correction in comparison with those treated with hand made from the original author of the brace MR, as report at SOSORT in Montreal.

These RSC scoliosis braces are delivered only by certified treatment centres or fitted by the manufacturer himself. The brace treatment system is integrated into an internationally established physiotherapy programme, the Barcelona Scoliosis Rehabilitation School (BSRS) concept, which was developed by MR and is based on the teaching of Katharina Schroth and Christa Lehnert-Schroth. This method also includes modifications from a French school [16].

#### 3.4.1 Measurements and Clinical photos

At least four clinical photos (4 clinical views) are required for the clinical documentation of each patient during the measurement process, fitting, and follow-up visits. This is facilitated

by utilising the Otto Bock LASAR posture apparatus to identify the pelvic, trunk and shoulder alignments.

### 3.5 Brace Design

The RSC braces for the subjects in this study were based on the original brace principles outlined in the RSC brace section of chapter 2. However, each subject in this study was assessed and evaluated individually, hence, the brace design was based on the individual characteristics of the subjects' scoliosis.

As an example of the thought process in how the brace is designed, subject 1 in the brace design section is provided to show how the scoliotic curves can change and how the appropriate RSC design needs to change accordingly.

Subject 1 presents with a 3-curve scoliosis, type A2 according to the Rigo classification of scoliosis (figure 1). The Cobb angle of the main thoracolumbar curvature was 49° prior to the start of treatment. The trunk imbalance was to the convex thoracic side with the collapse of the vertebral column on the concave side of the thoracic curve, as a result the shoulder was lower. The dorsal right and ventral left ribs humps can be seen clearly in the clinical presentation. In reference to the central sacral line (CSL), which is a vertical line from the center of the sacrum, the overhang is to the right and the prominence of the pelvis is presented on the left (figures 3.1a and 3.1b).

The brace corrects the collapsed thoracic concave side by the three-point pressure system in the coronal plane, producing the so-called mirror effect (Figure 3.1c).

The patient is overcorrected to the left by the brace and the vertebral column is straightened also, the ventral left rib hump is reduced. In order to open the collapsed thoracic concave side and to establish the three dimensional correctional mechanism, the shoulder of the thoracic concave side in type A2 curvatures (triple curvature) needs to be raised by the brace construction. The main thoracic curvature is corrected in the brace to a Cobb angle of 24°. The X-ray of the position in the brace shows that the ribs on the concave thoracic side are distinctly more “opened” than beforehand, and the CSL shows that the overhang to the right has been eliminated through the brace (figure 3.1d).

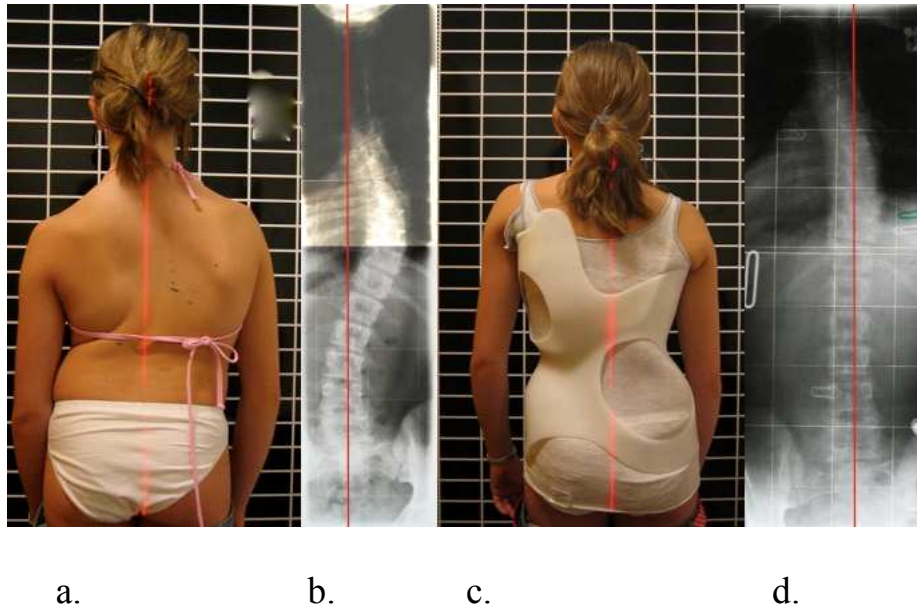


Figure 3.1 Posterior view of subject 1.

Figure 3.1a Pre-brace clinical photo.

Figure 3.1b Pre-brace X-ray of 49 degrees Cobb angle.

Figure 3.1c In-brace photo of patient wearing an A2 module RSC brace at 5 week follow-up.

Figure 3.1d In-brace X-ray presents with 24 degrees Cobb angle at the 5 week follow-up.

Subject 1 presents at the 8 month follow-up with improved symmetry of the trunk and as a result, the collapse of the thoracic concave side is significantly reduced and the shoulder position is balanced (figure 3. 2a). The out-of-brace X-ray shows a Cobb angle of 35° (figure 3.2b) , which has improved and corrected the position of the ribs in the concave area of the thoracic curvature.

Also, it was noted that the curve pattern has change from A2 type to C1 type curve pattern. Thus the brace design was also changed from an A2 module RSC brace to a C1 module RSC brace. As a result of this curve pattern change, the correctional principles do not require displacement of the pelvis; instead a central stabilisation can be seen. In comparison with the preceding A2 brace module, the left shoulder is not raised as much. This is because the collapsed thoracic concave side has improved and opened the right thoracic curve.

The laser line on the patient and the X-ray shows a slight decompensation to the left, caused by the varying stiffness of the curvatures and the correctional pressure of the scoliosis brace. The main curvature is corrected to an 18° Cobb angle in the RSC brace (figures 3.2c and 3.2d).

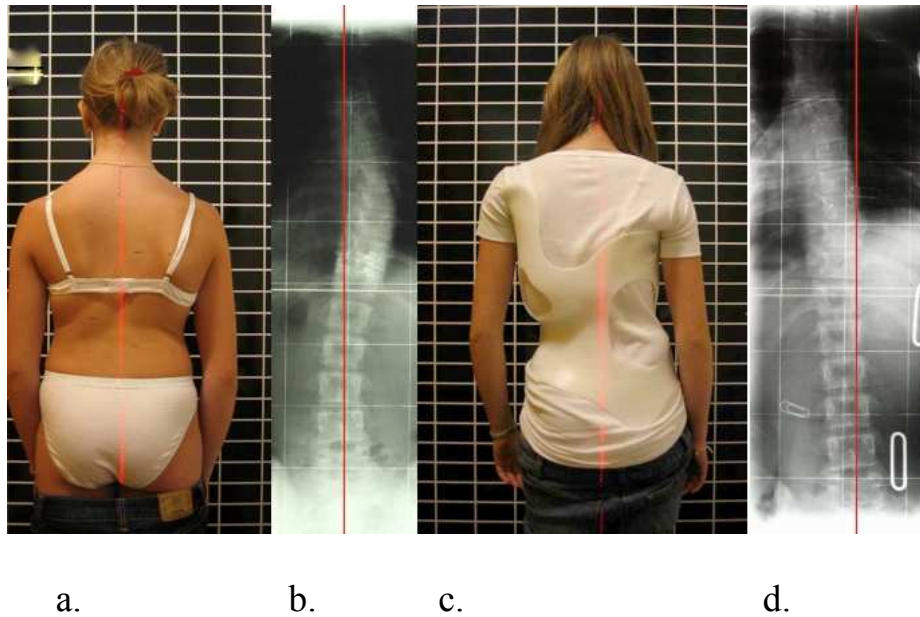


Figure 3.2 Posterior view of subject 1 at the 8 month follow-up.

Figure 3.2a The clinical photo shows an aligned and balanced clinical presentation.

Figure 3.2b Out of brace X-ray of 35 degrees Cobb angle.

Figure 3.2c In-brace photo of the patient wearing a C1 module RSC brace

Figure 3.2d In-brace X-ray presents with 18 degrees Cobb.

Both the clinical presentation and the X-ray findings show a stable condition after 15 months (figures 3.3a and 3.3b). The body alignment is almost in equilibrium. The Cobb angle of curvature is  $37^{\circ}$  without the orthosis (figure 3b). The patient continues treatment with a C1 type brace module.

As seen in figure 3c, the left axillary pad has again been raised somewhat in order to deflect the thoracic curvature even more. It can be seen clearly that the brace, through the three-point pressure system in the coronal plane (axillary pad, thoracic pad and lumbar pad), reduces the rib hump and produces the accompanying over-correcting postural deflection (figure 3.3c).



a.                      b.                      c.

Figure 3.3 Posterior view of subject 1 at the 15 month follow-up.

Figure 3.3a The clinical photo shows an aligned and balanced clinical presentation.

Figure 3.3b Out of brace X-ray of 37 degrees Cobb angle, C1 type curve.

Figure 3.3c In-brace photo of the patient wearing RSC brace.

A slightly worsened clinical situation presents 27 months later (figure 4). The pelvis projects noticeably more on the left, likewise involving a more noticeable collapse of the thoracic concave side. An observation of the shoulder girdle shows that the left shoulder has sunk down somewhat in comparison with figure 3.3a.

The X-ray confirms the new situation. Although the Cobb angle remains unchanged at 37 degrees, the curve pattern has changed (figure 3.4b) and correlates again with the situation at the beginning of treatment (changed from a C1 type to an A2 type curve pattern according to the Rigo classification). Therefore an A2 module RSC brace was designed and fabricated for the patient. The shift of the pelvis to the right and the deflection of the thoracic segment



produce the required postural overcorrection (mirror effect). At the beginning of treatment the marked deformities of the vertebrae and ribs can be seen clearly on the X-ray in figure 3.1b. The progression of the structural deformity of the ribs and vertebra of the thoracic curvature has been corrected. These orthoses modules have neutralized the unbalanced axial forces acting on the vertebrae and thus, made it possible for the bony structures to grow more evenly.

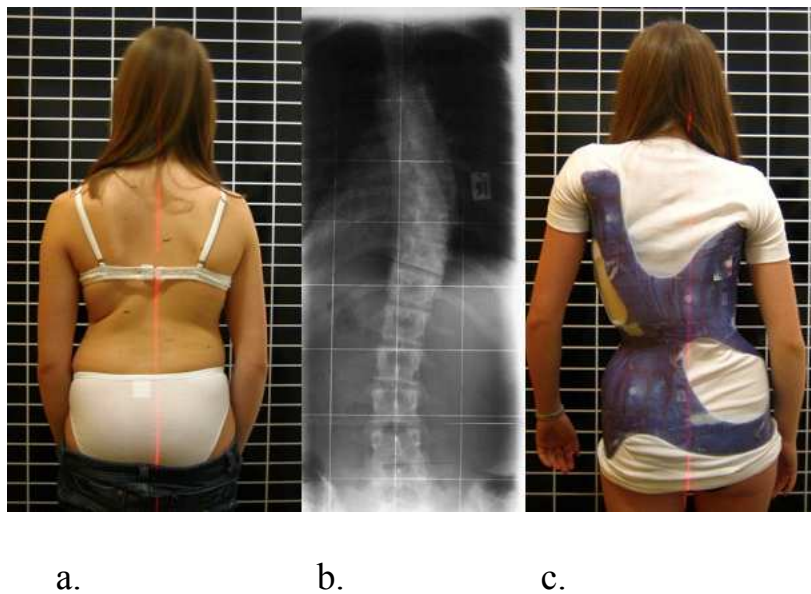


Figure. 3.4 Posterior view of subject 1 at the 27 month follow-up.

Figure 3.4a The clinical photo shows an aligned and balanced clinical presentation.

Figure 3.4b Out of brace X-ray of 37 degrees Cobb angle, A2 type curve.

Figure 3.4c In-brace photo of the patient wearing RSC brace.

#### 4. Results

The main group (n=147) and the SOSORT (RC) group (n=25) had a mean age of 12.97 and 12.32 respectively. The main group had 28 subjects with Cobb angles greater than 50 degrees with 17 male and 130 female subjects. The SOSORT (RC) group had no curves over 50 degrees and were all female, as outlined by SOSORT (RC) [12]. The significance level for all of the angles measured was  $p < 0.01$ .

##### Main Group

		mean	standard deviation	percent change
Thoracic Cobb Angle	before treatment	33.70	14.59	42.86%
	8 week follow-up	20.77	14.91	
Lumbar Cobb Angle	before treatment	28.18	13.71	41.78%
	8 week follow-up	17.47	14.02	
average % change:				42.32%

		mean	standard deviation	percent change
Major Cobb Angle	before treatment	36.52	13.31	47.71%
	8 week follow-up	20.82	14.59	
Minor Cobb Angle	before treatment	25.28	13.00	36.93%
	8 week follow-up	17.41	14.35	
average % change:				42.32%

Chart 4.1 The main group before treatment (initial) and at 8 week follow-up (primary correction) mean values, standard deviations and percent change for the thoracic, lumbar, major and minor Cobb angles.

**SOSORT Criteria Group**

		mean	standard deviation	percent change
Thoracic Cobb Angle	before treatment	21.88	8.20	54.35%
	8 week follow-up	10.32	11.83	
Lumbar Cobb Angle	before treatment	22.52	6.72	59.04%
	8 week follow-up	9.76	9.70	

average % change: 56.70%

		mean	standard deviation	percent change
Major Cobb Angle	before treatment	26.76	5.95	61.10%
	8 week follow-up	11.12	11.92	
Minor Cobb Angle	before treatment	17.64	5.83	52.30%
	8 week follow-up	8.96	9.47	

average % change: 56.70%

Chart 4. 2 The SOSORT (RC) before treatment (initial) and at 8 week follow-up (primary correction) mean values, standard deviations and percent change for the thoracic, lumbar, major and minor Cobb angles.

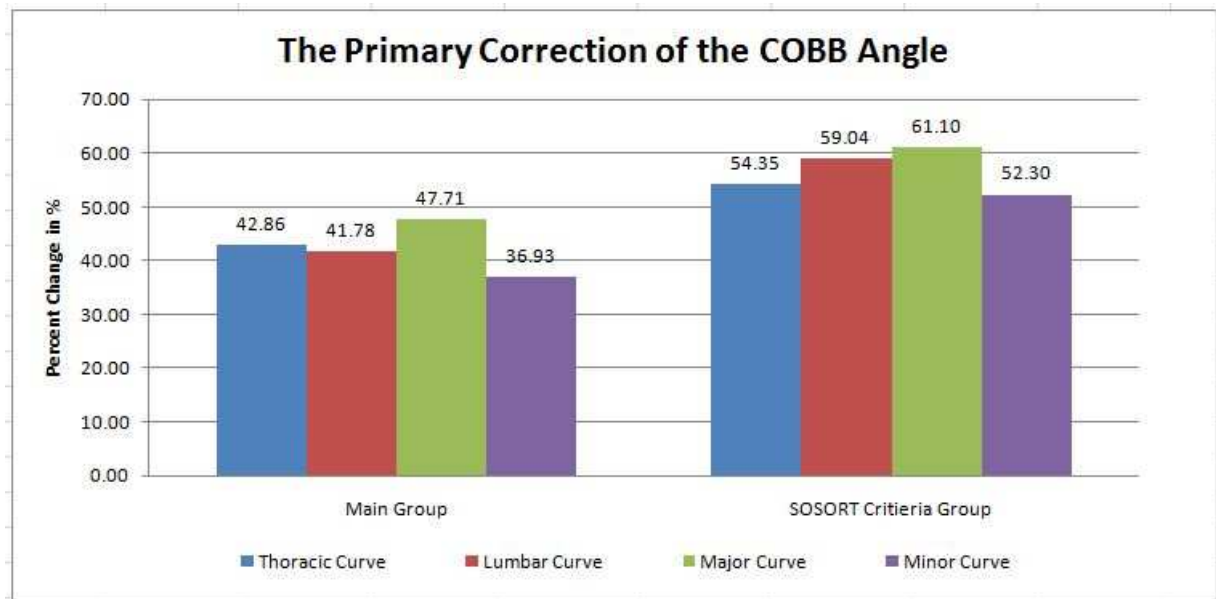


Figure 4.1 The major, minor, thoracic and lumbar curves' primary correction of the Cobb angles with the RSC brace. The main group's primary correction was 43 degrees, 42 degrees 48 degrees and 37 degrees for thoracic, lumbar, major, and minor curve, respectively. The SOSORT group's primary correction was 54 degrees, 59 degrees, 61 degrees and 52 degrees for thoracic, lumbar, major, and minor curve, respectively.

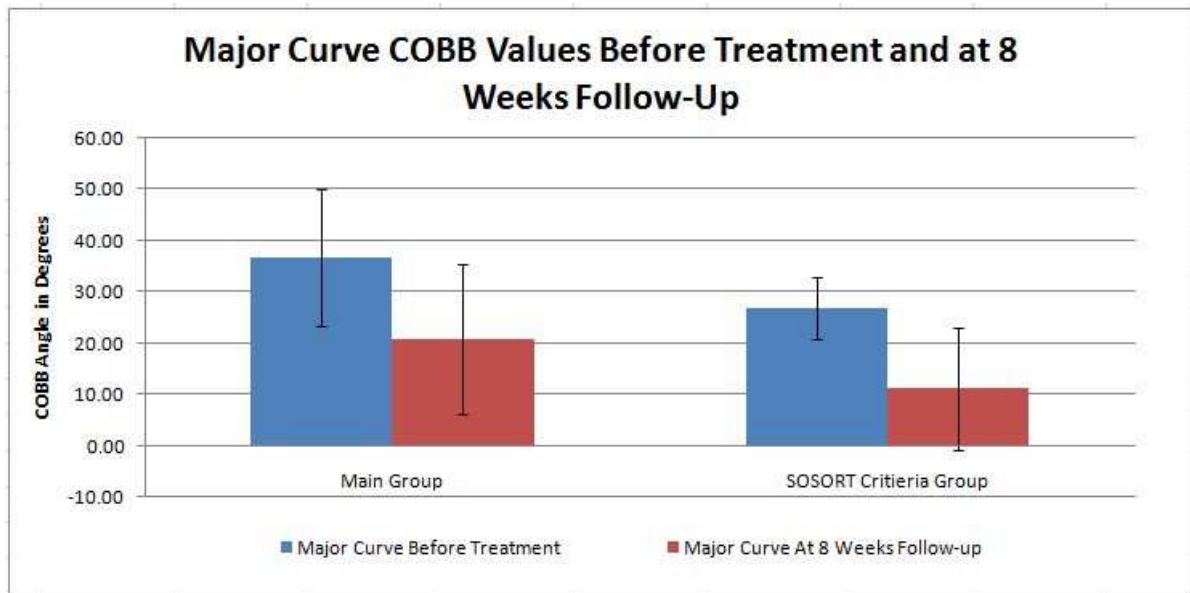


Figure 4.2 The major Cobb angle measured from the X-ray before treatment and at the 6 to 8 week follow up (primary correction) with the RSC brace.

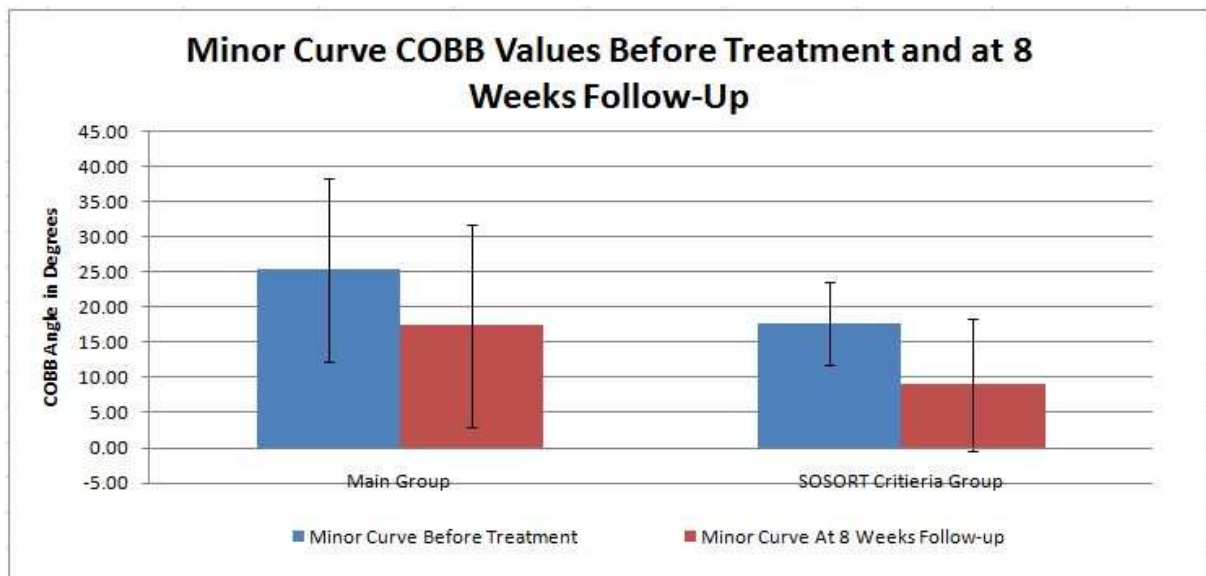


Figure 4.3 The minor Cobb angle measured from the X-ray before treatment and at the 6 to 8 week follow up (primary correction) with the RSC brace.

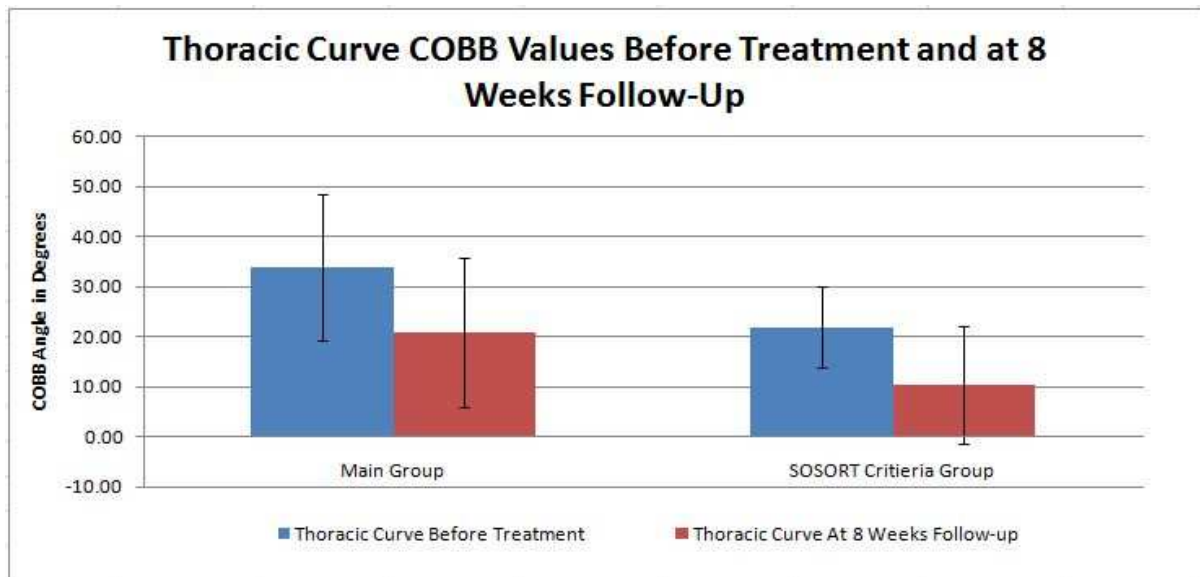


Figure 4.4 The thoracic Cobb angle measured from the X-ray before treatment and at the 6 to 8 week follow up (primary correction) with the RSC brace.

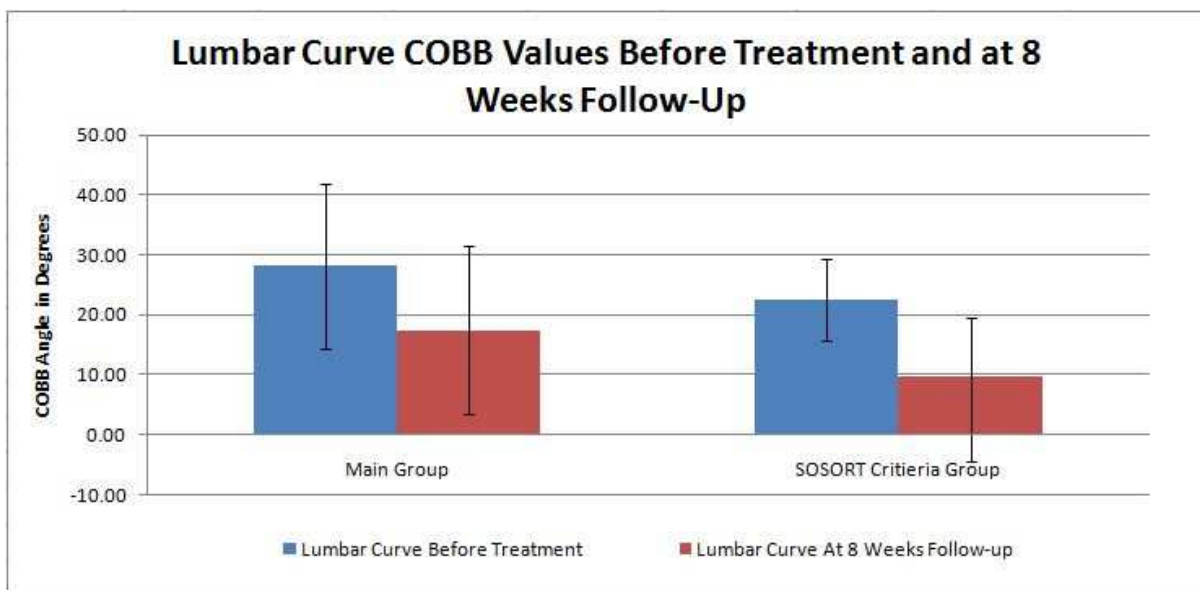


Figure 4.5 The lumbar Cobb angle measured from the X-ray before treatment and at the 6 to 8 week follow up (primary correction) with the RSC brace.

## 5. Discussion

The results are consistent with the experimental hypothesis: those subjects who were treated with the RSC brace reported a significant primary correction of the major, minor, thoracic and lumbar Cobb angles for both the main and SOSORT (RC) groups.

When the subject's X-ray values were measured for the main group (n=147), the means were 36.52 degrees and 20.82 degrees before treatment and primary correction respectively for the major Cobb angles as well as 25.28 degrees and 17.41 degrees before treatment and primary correction respectively for the minor Cobb angles. The in-brace primary corrections for the major and minor Cobb angles were 47.71% and 36.93% respectively for the main group. The in-brace primary corrections for the thoracic and lumbar Cobb angles were 42.86% and 41.78% respectively for the main group.

When the subject's X-ray values were measured for the SOSORT group (n=25), the means were 26.76 degrees and 11.12 degrees before treatment and primary correction respectively for the major Cobb angles as well as 17.64 degrees and 8.96 degrees before treatment and primary correction respectively for the minor Cobb angles. The in-brace primary corrections for the major and minor Cobb angles were 61.10% and 52.30% respectively for the SOSORT group. The in-brace primary corrections for the thoracic and lumbar Cobb angles were 54.35% and 59.04% respectively for the SOSORT group. The standard error in the experiment was small, hence it did not affect the results.

The primary in-brace correction results were obtained at the 8 weeks follow up, these results can be related to the end of treatment results. Therefore, since the initial in-brace X-rays

presented with favourable results, it could be predicted that the RSC brace prevents curve progression at the end of treatment. The main group of subjects were older, higher Risser signs, larger initial curves which were more structural and difficult to correct compared with the SOSORT group.

The rationale of presenting the two groups of subjects was to show that even though the main group of subjects were clinically and radiological more difficult to treat, they still had significant primary corrections. The SOSORT group of patients had the most significant primary corrections of 61.10% and 52.30% for the major and minor curves which was related to the strict restrictive criteria that limited and controlled the subject types.

Conventionally, excellent scoliosis correction was considered when the vertebral column in the coronal plane, had a 50% correction and was as close as possible to vertical. However, often significant in-brace primary correction of the Cobb has been achieved at the cost of having negative effects to the sagittal plane by increasing the thoracic hypokyphosis, also known as flatback and without regard for the rotational correction. The three-dimensional deformity of scoliosis needs to be evaluated and treated in all three anatomical planes. When more influence is put on the sagittal plane and rotational correction, the coronal plane deformity, however, does not become less important, as the coronal radiograph is still considered as standard good correction [7]. However, it would be disadvantageous to flatten out and straighten the spine in all planes (sandwich effect) simply to achieve maximum coronal plane correction. As radiologically, good correction of only the coronal plane has often been the medical team's primary focus, oftentimes, this places a negative influence on the other planes, resulting in deformities such as flatback and poor clinical presentation of pelvis, trunk and shoulders.



## 6. Conclusion

The present experiment focused on X-ray measurements of idiopathic scoliosis subjects before treatment and the primary correction with the RSC brace. The results are based on a sample size of 147 subjects in the main group and 25 subjects in the SOSORT (RC) group. As a result, the RSC brace system had significant primary corrections in both the main and SOSORT groups. Therefore, since the initial in-brace X-rays presented with favourable results, it is predicted that the RSC brace prevents curve progression at the end of treatment.

Further investigation is then warranted to analyse the RSC brace with matched samples to determine if the brace corrections are the same in different teams using this system, as this study has been conducted from a matched series from teams in Barcelona and Germany. Furthermore, a long term follow-up of results would be ideal to determined the results at the end of treatment, rather than just at the first follow-up appointment 6-8 weeks into treatment.

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